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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590

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Stephen L. Grant
Oldham & Oldham Co., L.P.A.
Twin Oaks Estate
1225 West Market Street
Akron, OH 44313-7188

EXAMINER

BRADFORD, RODERICK D

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 07/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/726,499

Applicant(s)

SCHAUERTE, PATRICK

Examiner

Roderick Bradford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2000.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed April 9, 2003 have been fully considered but they are not persuasive.

With respect to the Mehra, Machek and Spreigel references the arguments are not persuasive since the lumen in each reference does not impede blood flow, but rather it's what's in the lumen in each reference that impedes blood flow. Therefore all of the rejections stand since each reference meets the broad claim limitations.

With respect to the Mehra reference, the argument that Mehra wire unit is not "tubular" is not persuasive since Mehra states that "expandable electrodes taking the form of expandable tubular meshes" (see column 6, line 68 and column 7, lines 1-3).

With respect to the Dahl reference, the argument is not persuasive since Dahl also allows for blood to flow unimpeded (see column 5, lines 1-16).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application

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being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehra et al. U.S. Patent No. 5,170,802.

Referring to claim 1, Mehra discloses an electrode for intravascular stimulation, cardioversion and/or defibrillation comprising:

- A stimulation probe which can be fixed in a blood vessel by way of electrical or magnetic pulses and cardioversion/defibrillation shocks can be delivered (column 2, lines 52-57)
- Wherein a metallic, electrically conductive tubular wire unit adjoins the feed line in the axial direction (Fig. 4 and column 5, lines 1-3)
- Forms an expansion body that can be deployed in the corresponding vessel and bears against the wall of the vessel from the interior thereof under expansion (column 2, lines 9-13).

Referring to claim 2, wherein the inflatable balloon body is provided for expansion in the interior wire, which is plastically deformable (abstract).

4. Claims 1, 3, 8, 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Dahl et al. U.S. Patent No. 5,531,779.

Referring to claim 1, Dahl discloses an electrode for intravascular stimulation, cardioversion and/or defibrillation comprising:

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- A stimulation probe which can be fixed in a blood vessel by way of electrical or magnetic pulses and cardioversion/defibrillation shocks can be delivered (column 2, lines 3-7)
- Wherein a metallic, electrically conductive tubular wire unit adjoins the feed line in the axial direction (column 2, lines 42-45)
- Forms an expansion body that can be deployed in the corresponding vessel and bears against the wall of the vessel from the interior thereof under expansion (column 3, lines 46-52).

Referring to claim 3, wherein the wire unit resiliently expands itself from a pre-stressed compressed condition inside the vessel (column 4, line 6-10).

Referring to claim 8, wherein a radial diameter of the wire unit changes in the longitudinal direction (Fig. 3).

Referring to claim 9, wherein the wire unit is of a conical type (column 4, lines 3-10).

Referring to claim 13, wherein a control unit is electrically communicated to the wire unit provides at least one control signal thereto (column 2, lines 20-29).

5. Claims 1, 4, 5, 8, 12 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Machek et al. U.S. Patent No. 5,954,761.

Referring to claim 1, Machek discloses an electrode for intravascular stimulation, cardioversion and/or defibrillation comprising:

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- A stimulation probe which can be fixed in a blood vessel by way of electrical or magnetic pulses and cardioversion/defibrillation shocks can be delivered (column 2, lines 3-7)
- Wherein a metallic, electrically conductive tubular wire unit adjoins the feed line in the axial direction (column 2, lines 42-45)
- Forms an expansion body that can be deployed in the corresponding vessel and bears against the wall of the vessel from the interior thereof under expansion (column 3, lines 46-52).

Referring to claim 4, wherein the entire wire unit acts as a unipolar stimulation pole (column 4, lines 18-25 and column 7, lines 10,11).

Referring to claim 5, wherein the wire unit is a cylindrical coil (column 7, lines 8-10).

Referring to claim 12, wherein a further portion of the feed line extends in the axial direction parallel at least to a portion of the wire unit, such portion is electrically insulated relationship therewith (column 4, lines 18-21).

6. Claims 1, 3, 4, 15 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Spreigl et al. U.S. Patent No. 6,161,029.

Referring to claim 1, Spreigl discloses an electrode for intravascular stimulation, cardioversion and/or defibrillation comprising:

- A stimulation probe which can be fixed in a blood vessel by way of electrical or magnetic pulses and cardioversion/defibrillation shocks can be delivered (column 5, lines 12-17)

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- Wherein a metallic, electrically conductive tubular wire unit adjoins the feed line in the axial direction (column 5, lines 18-17)
- Forms an expansion body that can be deployed in the corresponding vessel and bears against the wall of the vessel from the interior thereof under expansion (column 5, lines 5-10).

Referring to claim 3, wherein the wire unit expands itself from a pre-stressed position (column 5, lines 60-64).

Referring to claims 4 and 18, wherein the surface of the wire unit acts as a unipolar stimulation pole (column 7, lines 50-54).

Referring to claim 15, wherein the balloon body is hydraulically inflatable (column 11, lines 40-44).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 7, 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Machek et al. U.S. Patent No. 5,954,761 in view of Laufer et al. U.S. Patent No. 6,283,989.

Referring to claims 7, 11 and 16, Machek fails to disclose a device wherein an induction unit supplies the electrode with voltage and inductively heats the electrode. However, Laufer discloses a device wherein an induction unit supplies the electrode

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with voltage and inductively heats the electrode (column 2, lines 32-37) as a means to more efficiently provide energy to the electrode.

It would have been obvious to one having ordinary skill in the art to modify the teachings of Machek to include wherein an induction unit supplies the electrode with voltage and inductively heats the electrode, as taught by Laufer, as a means to more efficiently provide energy to the electrode.

9. Claims 10 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra (or Dahl or Machek or Spreigl) et al. U.S. Patent No. 5,170,802.

Referring to claims 10 and 17, Mehra (or Dahl or Machek or Spreigl) discloses the claimed invention except for wherein the wire unit is coated with a medicant. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the wire unit as taught by Mehra (or Dahl or Machek or Spreigl), with medicant since it is well known in the art that leads include a medicant to help reduce the stress on blood vessels caused by the insertion of the lead.

10. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra et al. U.S. Patent No. 5,170,802.

Referring to claims 14 and 15, Mehra discloses the claimed invention except for wherein the balloon body is pneumatically or hydraulically inflatable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Mehra, to include a balloon body that is pneumatically or hydraulically inflatable since it was known in the art that these two procedures are used as alternative means to inflate the balloon body.

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11. Claim 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra (or Dahl or Machek or Spreigl) et al. U.S. Patent No. 5,170,802.

Referring to claim 19, Mehra (or Dahl or Machek or Spreigl) discloses the claimed invention except for wherein the feed line is terminated with a ring to form a bipolar electrode. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the feed line of Mehra (or Dahl or Machek or Spreigl), with a ring to form a bipolar electrode since it was well known to use bipolar electrodes as a more efficient way of sensing and stimulating the heart.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sutton et al. U.S. Patent No. 6,529,779.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

R. Bradford
R.B. 7/2/03
July 2, 2003

GEORGE R. EVANISKO
PRIMARY EXAMINER
7/1/3